

**Maryland Board of Pharmacy
Public Board Meeting**

**Agenda
March 18, 2020**

Name	Title	Present	Absent
Ashby, D.	Commissioner		
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Fink, K.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner/Secretary		
Singal, S.	Commissioner		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Management Associate		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)										
I. Executive Committee Report(s)	A.) K. Morgan, Board President B.)K. Rusinko, Secretary	Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda. 1. Call to Order 2. Sign-in Introduction and of meeting attendees – (Please indicate on sign-in sheet if you are requesting CE Units for attendance) 3. Distribution of Agenda and packet materials 4. Review and approve February 2020 Public Meeting Minutes											
II. A. Executive Director Report	D. Speights-Napata, Executive Director	1. Welcome to new board member Kristen Fink 2. Corona Virus Update											
B. New Business	K. Morgan, Board President	1.											
C. Operations	E. Fields, Deputy Director/ Operations	1. Procurement and Budget Updates a: February 2020 Financial Statements 2. Management Information Systems (MIS) Unit Updates a: New Pharmacy application is ready for renewals											
D. Licensing	E. Bouyoukas, Commissioner	1. Unit Updates 2. Monthly Statistics <table><tr><td>License Type</td><td>New</td><td>Renewed</td><td>Reinstated</td><td>Total</td></tr><tr><td>Distributor</td><td>18</td><td>0</td><td>0</td><td>1,375</td></tr></table>	License Type	New	Renewed	Reinstated	Total	Distributor	18	0	0	1,375	
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E. Compliance	T. Leak, Compliance Director	<div>1. Unit Updates</div> <div>2. Monthly Statistics</div> <div>Complaints & Investigations:</div> <div>New Complaints - 41</div> <div><div>• Customer Service – 2</div><div>• HIPPA and Fraud – 1</div><div>• Dispensing Error – 3</div><div>• Inspection Issues – 23</div></div>																																									

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A. Practice Committee	Evans, K. Commissioner	<p>Rob Wray - What is the Maryland Board of Pharmacy's plan to help prevent the issues brought up in this NY Times article. Clearly this is a national problem as well as a Maryland problem, but I'm sure there is something that can be done for Marylanders at the state level.</p> <p>https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html</p> <p>Proposed response:</p> <ol style="list-style-type: none"> 1. The Board provides information and education through the Board's newsletter. 2. The Board reviews all medication error complaints that it receives. 3. The Board provides letters of education in response to questions and complaints received. 4. The Board requires pharmacists to complete continuing education related to medication errors during each license renewal cycle. <p>Kristopher Gleason – Wegmans School of Pharmacy (NY) - I am reaching out on behalf of Wegman's School of Pharmacy at St. John Fisher College, located in Rochester, New York. The school is planning to add an online pathway to their Doctor of Pharmacy program and is concerned that doing so may impact a graduate's ability to become a pharmacist licensed within this state. I am hoping you can assist me with the following questions:</p> <ol style="list-style-type: none"> 1. Will students completing the online pathway of an out-of-state, ACPE accredited pharmacy program be eligible to register as interns for the purposes of completing their internship within this state? <p>Proposed response:</p>	

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		<p>1. No, students completing an online out of state ACPE accredited pharmacy program will not be eligible to register as interns in this state for the purposes of completing their internship within this state?</p> <p>2. No, there are no specific deadline due as they are not eligible. See response to question (#1)</p> <p>3. Yes, a student may apply to the Maryland Board for licensure.</p> <p>If the students are doing hours as part of the rotation, a registration is not required in Maryland; however, if it is a paid position an Intern registration is required.</p> <p>John (Jay) - I am inquiring about a scenario regarding refills of a prescription.</p> <p>In January, Doctor A from a medical practice writes a prescription for a 1 month supply with 2 refills.</p> <p>In February, Doctor B from the same medical practice writes the exact same prescription for 1-month supply with 1 refill.</p> <p>Proposed response: Your understanding of the scenario is correct.</p> <p>A total of three fills of one prescription may be filled between Doctor A and Doctor B.</p> <p>You may hold the prescription as long as it was written within the last 120 days.</p> <p>Julia McDonnell-Greater Baltimore Medical Center - Our MRI department is outsourced by Advanced Radiology, is attached to our physical hospital by a hallway (but contains a different physical address), services both inpatients and outpatients, and is considered non-regulated space. For inpatients who need an MRI, their inpatient nurse from the unit dispenses any medications they might need while in MRI from their unit's Omnicell cabinet (including narcotics, anxiety medications, etc.). The nurse then walks with these</p>	

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		<p>medications in his/her pocket while he/she is transporting the patient to MRI. In the event that these medications are needed, he/she will administer them in MRI to the patient.</p> <p>MRI is requesting an Omnicell cabinet for their area, in which they can keep these few medications (<5) so that the inpatient nurse will not have to travel from the unit with them. This Omnicell will only be used for inpatients (outpatients who need medications during the procedure will be instructed to bring the medication with them from home).</p> <p>Areas where we are seeking your guidance:</p> <ul style="list-style-type: none"> • Can we install an Omnicell that we are restocking in a non-regulated space, if it is servicing inpatients? • Can we restock this Omnicell with narcotics if they are at a different physical address than our hospital's DEA number in which the medications are purchased? <p>Proposed response: The Board of Pharmacy does not regulate physicians. The conduct that you have described would need to be performed under a physician dispensing permit issued by the Maryland Board of Physicians.</p> <p>For more information on physician dispensing permits and the scope of practice for physicians in Maryland, please contact the Maryland Board of Physicians at 410-764-4777.</p> <p>Douglas Hosie – Anna Arundel Medical Center - The Anna Arundel Medical Center and Doctors Hospital have joined forces to create Luminis Health Inc. We are working on combining our Employee Benefits package for our system.</p> <p>Anna Arundel Medical Center has an Employee Pharmacy that fill medications for the current employees of Anna Arundel Hospital.</p>	

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		<p>We would like to fill Medications for the Doctor's Hospital employees at the same location and deliver them to Doctors Hospital Pharmacy (Inpatient Pharmacy) for pick up.</p> <p>Reading the Maryland Pharmacy Laws book chapter 25.02 definitions, “ (b) “Depot” does not include: (i) A Licensed Health Care Facility.”</p> <p>Doctors Hospital is a Licensed Health Care facility so our Interpretation that it would not be a “Depot” and having the Doctors Hospital Pharmacy hold the medication for pick up would be permissible.</p> <p>(Signed Logs of pickup and records of delivery will be kept, Pharmacist on site for questions 24/7)</p> <p>Please let us know if we have missed something that would put us out of regulatory compliance by implementing this plan.</p> <p>Proposed response: No, your interpretation is correct. Under COMAR 10.34.25.04; A pharmacy may not knowingly deliver prescription medications to a depot, or establish or cooperate in the establishment of a depot.</p> <p>Jasmine Dickerson – Affinity Patient Coordination - I would like clarification on the licensure requirements for a non-resident pharmacist conducting medication adherence assessment and chronic disease state education for targeted populations. These services are not conducted from a retail pharmacy or a facility that dispenses or processes prescriptions in any way and are completely separate from the dispensing process. Could you clarify what the requirements are in order to conduct these services in Maryland by pharmacists licensed in other states? I have listed my specific questions below.</p> <ol style="list-style-type: none"> 1. Is licensure required in [insert state here] for non-resident pharmacist counseling services conducted by pharmacists licensed in other states? 	

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		<p>2. If so, is a new state-specific MPJE required to reciprocate?</p> <p>3. Is there eligibility for a Pharmacist in Charge to be licensed in Maryland and have other staff members conduct counseling services?</p> <p>Proposed response:</p> <ol style="list-style-type: none"> 1. Yes, a pharmacist is required to be licensed to counsel patients in Maryland. 2. To become licensed in Maryland as a pharmacist by reciprocity, you are required to take the MPJE examination administered by NABP. 3. No, Maryland does not have a regulation recognizing pharmacist in charge. <p>Tracey Linton – Technician - Alpha is offering a class in March teaching technician how to administer vaccines in Maryland. Does this mean that technicians in Maryland will soon be able to administer vaccines as well?</p> <p>Proposed response: At the present time Maryland does not have a regulation allowing technicians to administer vaccines.</p> <p>Jermaine Smith – Rite Aid Pharmacy - I was wondering if you could point me in the right direction. The company is considering establishing a mandatory 30-minute lunch/rest period for our pharmacists. In our research we have found that some states would allow registered technicians to remain in the pharmacy to process scripts and allow patients to pick-up re-filled prescriptions.</p> <p>Since establishing registration for technicians and interns would we be allowed to have the registered technicians or interns remain in the pharmacy or would we be required to close the pharmacy completely during that 30-minute lunch/rest period?</p>	

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		<p>Proposed response: Health Occupation reference 12-101: Technicians must be directly supervised by a licensed pharmacist. Under Md. Code Ann., Health Occ. § 12-101(i), “direct supervision” means that a licensed pharmacist is physically available on-site. Therefore, pharmacists may take breaks provided that they are immediately available.</p> <p>COVID-19 Guidance Information: To prevent the spread of COVID-19 (Coronavirus), Governor Hogan declared a State of Emergency on March 5, 2020. The Governor subsequently issued Executive Orders on March 12 and 16, 2020, which contain provisions affecting the Board and its licensees. Currently, all pharmacies should remain open if able. As this situation evolves, pharmacists and pharmacies should continue to provide services in a manner that assures access and safety.</p> <p>The Maryland State Board of Pharmacy (the “Board”) would like to provide the following information and guidance regarding compliance with the Maryland Pharmacy Act during the declared State of Emergency:</p> <p><u>All Pharmacies</u></p> <ul style="list-style-type: none"> • Review or create interim emergency policies to anticipate and react to this emergency and disseminate to all staff. It is recommended to incorporate recommendations in the CDC’s Interim Guidance for Employers and additional guidance and information for pharmacies on the APHA and ASHP websites. • Keep up to date with the state of conditions in Maryland. • If required by or requested of the pharmacy, the FDA has provided a temporary Guidance Document on a Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency in accordance with USP 795 standards. • If able, consider facilitating prescription dispensing at curbside or drive-through pickup. 	
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		<ul style="list-style-type: none"> Consistently monitor the health of pharmacy staff. Any staff member exhibiting flu-like symptoms or respiratory illness should stay at home. <p><u>Remote Processing</u></p> <ul style="list-style-type: none"> In order to support the Governor and Secretary of Health with their directives to telework and social distance to the extent possible, the Board will not enforce requirements regarding the direct supervision of pharmacy technicians by a licensed pharmacist if the technicians are engaged in remote processing of delegated pharmacy acts. Remote processing of delegated pharmacy acts includes prescription or order entry, other data entry, and may also include insurance processing and other administrative functions. Pharmacists currently have the ability to engage in remote processing, which may also include clinical functions such as drug utilization review, authorizing release of medications from automated medication systems, providing drug information, and other similar pharmaceutical services. Remote processing does not include the physical handling of any prescription drugs or devices. <p><u>Refills</u></p> <ul style="list-style-type: none"> The Maryland Pharmacy Act, Sec. 12-506(c), allows a pharmacist, during a state of emergency, to refill a prescription for which a refill has not been authorized if: (1) the pharmacist is unable to obtain authorization from the prescriber; (2) the refill is not for a controlled dangerous substance; (3) the quantity dispensed does not exceed a 30-day supply or unit of use; and (4) the pharmacist notifies the prescriber of the refill within 7 days. <p><u>Sterile Compounding</u></p> <ul style="list-style-type: none"> Follow established, recognized guidelines (CDC, CDC on N95 Respirators, FDA, or equivalent) for guidance on conserving garb and 	

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		<p>alternatives and strategies for managing potential extended use of face masks, gowns, and shoe covers. It is recommended that pharmacies keep a copy of the guidance used to adjust practice and to continue to follow protocols which prohibit the use of contaminated or unusable supplies.</p> <ul style="list-style-type: none"> • Please note, at a minimum, weekly surface sampling inside an ISO-5 space is highly recommended when garbing in a manner that is not consistent with USP standards. The Board understands budgetary constraints and suggests following the 2019 USP 797 standards on environmental sampling and organism identification. • The Board recognizes the need to delay certain activities such as personnel annual competencies or other quality assurance activities in order to reduce supply needs. Inspectors are aware of the challenges being presented to pharmacies and will take these into account when inspecting pharmacies. • If you use a compounding aseptic isolator, regulation 10.34.19.13(B) states: "The requirements of this regulation [10.34.19.13(A) Garbing] are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with USP 797 Standards and isolator vendor/manufacturer specifications." <p><u>Licensing</u></p> <ul style="list-style-type: none"> • Pursuant to an Executive Order issued by Governor Hogan on March 12, 2020, all licenses, registrations, and permits issued by the Board set to expire during the state of emergency and catastrophic health emergency shall be extended to the 30th day after the date the state of emergency is terminated and the catastrophic health emergency is rescinded. No late fees or reinstatement fees will be imposed during this time period. To the extent it is able, the Board will accept and continue to process renewal applications during the state of emergency and catastrophic health emergency. • In keeping with the Governor's policy extending expiration dates for licenses, and maintaining the ability of the pharmacist workforce to 	

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		<p>administer influenza and other CDC-recommended vaccinations, the Board will not take enforcement action based on expired or inactive CPR certifications held by pharmacists registered to administer vaccinations if the CPR certification becomes inactive or expires during the state of emergency. Upon the termination of the state of emergency, the Board will allow affected pharmacists 30 days to update their live CPR certification.</p> <ul style="list-style-type: none"> • Pursuant to an Executive Order issued by Governor Hogan on March 16, 2020, any pharmacist or pharmacy technician actively licensed in another state or with an expired license or registration issued by the Board may be able to work in a health care facility (the definition of which does NOT include a pharmacy) in Maryland under certain circumstances. • The Board will not impose the 30-day notice requirement associated with a change of business hours for a permitted pharmacy or wholesale distributor pursuant to COMAR 10.34.30.05(A). The Board will instead require advanced notice as soon as practicable if an establishment location is forced to change its hours or temporarily close. Please note that all other requirements still apply, such as notice to patients, transfer of prescriptions, and documentation of transfers of any drug inventory. <p>Any changes to pharmacy practice should only be viewed as short term solutions to deal with the current crisis. All policies should return to normal practice as the crisis begins to resolve. This event is not an excuse to lower quality assurance standards, and the Board expects all of its pharmacies to uphold and follow practices and policies which ensure utmost patient care and safety while aiding in preventing the spread of COVID-19.</p>	

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B. Licensing Committee	D. Ashby, Chair	<p>1. Review of Pharmacist Applications:</p> <p>a. 124776 - The applicant is requesting to be granted eligibility to retake the NAPLEX for a 7th attempt. (5 failed attempts with the New York Board of Pharmacy and 1 failed attempt with MDBOP, which was approved for a 6th attempt of the NAPLEX exam on the 11/21/2018 Board agenda) Committee's recommendation: Approve</p> <p>b. 124688 - The applicant has two previous MDBOP expired Initial exam applications. The applicant has 2 failed MPJE exam score reports, 1 expired passing MPJE exam score report and 2 withdrawn NAPLEX eligibility granted by the MDBOP. The applicant is requesting an extension for her testing accommodations deadline, which is due to expire July 2020. Committee's recommendation: Approve, testing accommodations until 02/12/2021</p> <p>c. 124659 - The applicant is requesting the Board grant him an extension of his NABP License Transfer Application and grant him eligibility to retake the MPJE exam for a 6th attempt. Committee's recommendation: Deny, preliminary application request and approve 6th MPJE exam attempt</p> <p>d. 122033 - The applicant is requesting the Board to grant him an extension of his NAPLEX score report via email, which expired on 11/21/2019. He took and passed the MPJE on 02/21/2020. Committee's recommendation: Approve</p>	

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		<p>e. NK 112449 - Pharmacist is requesting a waiver of the reinstatement requirement. Her license expired 12/31/2019. She alleges that due to online renewal issues with the Board's website she was not allowed to renew. <i>Committee's recommendation: Deny</i></p> <p>f. GOS- The licensee is still requesting a refund of his reinstatement application fee. The Board requested that the licensee submit proof of his 30 CE hours and he has not submitted the requested documentation. Per the NABP CE Monitoring portal only shows proof of 10.5 completed CE hours. The licensee was contacted via phone by the Board 02/20/2020. There is no new information for the licensee's refund request. <i>Committee's recommendation: Deny</i></p> <p>g. RK - The soon to be MDBOP applicant is a foreign graduate. She states that she passed the FPGEE exam in 2014 and passed the NAPLEX exam in 2018. She was also able to meet the TOEFL Score requirement in December 2019. She passed all the exams required to become FPGEC certified, but unfortunately the FPGEE exam expired in April 2019.</p> <p>She is requesting the Board grant her an extension of her FPGEE score in order to complete the NABP requirements to be certified and to please allow her to take the MPJE exam in order to obtain her license in Maryland. <i>Committee's recommendation: Approve</i></p> <p>2. Review of Pharmacy Intern Applications:</p>	

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		<p>a. AN - Registrant is requesting an extension of her Pharmacy Intern-Student registration which expired 01/31/2020. <i>Committee's recommendation: Approve until 12/31/2020</i></p> <p>3. Review of Pharmacy Technician Applications: NONE</p> <p>4. Review of Distributor Applications:</p> <p>a. Medivant Health - Registered FDA 503b facility is requesting a waiver of the FDA inspection requirement. In lieu of submitting the FDA inspection, the company would provide a copy of the AZ inspection report. Once the FDA inspection is conducted they will then provide a copy to the Board. <i>Committee's Recommendation: Deny</i></p> <p>5. Review of Pharmacy Applications: NONE</p> <p>6. Review of Pharmacy Technicians Training Programs: NONE</p> <p>7. Continuing Education Requests:</p> <p>a. KSI - About the Glucose Monitor (3 hours) <i>Committee's recommendation: Deny, inadequate documents or materials.</i></p> <p>b. KSII - About Epilepsy (3 hours) <i>Committee's recommendation: Deny</i></p> <p>c. KSIII - About Allergies (3 hours)</p>	

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		<p><i>Committee's recommendation: Deny</i></p> <p>d. KSIV - About Compounding (3 hours) <i>Committee's recommendation: Deny</i></p> <p>e. KSV - About Nuclear Pharmacy (3 hours) <i>Committee's recommendation: Deny</i></p> <p>f. KSVI - Patient Safety-Importance of Aseptic Technique (3 hours) <i>Committee's recommendation: Deny</i></p> <p>g. KSVII - Law About HIPPA (3 hours) <i>Committee's recommendation: Deny</i></p> <p>h. LGI - NADDI Maryland Chapter Training 2019 (6 hours) <i>Committee's recommendation: Approve 5 hours</i></p> <p>i. LGII - NADDI Maryland Chapter Training 2018 (7 hours) <i>Committee's recommendation: Approve 5.5 hours</i></p> <p>j. AD - An update on the Drug Epidemic: The Crucial Roles of Physicians (2 hours) <i>Committee's recommendation: Deny, no content for pharmacist.</i></p> <p>8. New Business:</p> <p>a. Spectra Medical Devices Inc - Wholesale Distributor is requesting the Board consider Massachusetts as a reciprocal state. <i>Committee's recommendation: Tentative approval pending verification of inspection process.</i></p>	

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C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update:	
D. Disciplinary	J. Hardesty, Chair	Disciplinary Committee Update	
E. Emergency Preparedness Task Force	N. Leikach, Chair	Emergency Preparedness Task Force Update	
IV. Other Business & FYI	K. Morgan, President		
V. Adjournment	K. Morgan, President	<p>A. The Public Meeting was adjourned.</p> <p>B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.</p> <p>C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.</p>	

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		D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.	